Ethics of undisclosed payments to doctors recruiting patients in clinical trials

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Financial advisers who sell you insurance or mortgages are required by the rules to tell you how much commission they will earn as a result of your custom. But doctors who ask patients under their care to take part in a clinical trial are under no obligation to reveal how much they might earn as a result of their patients agreeing to take part in the trial. Can this be right?

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Of course, the situation is not quite as simple as this. Selling insurance, one could argue, is not the same as inviting a patient to take part in a clinical trial. If the doctor was not reimbursed generously for his time then important clinical research would just not get done.[1] The doctor can be trusted to put the best interests of the patient above personal gain, and therefore telling potential trial subjects how much the doctor will be paid is unnecessary. Do these arguments stand up to closer scrutiny? Or has the practice and scale of payments reached a point where it has become harmful to the conduct of good research?

Randomised clinical trials, often sponsored by pharmaceutical companies with a valid commercial as much as a genuinely scientific interest, are the only reliable way to generate good quality evidence of efficacy.[2] Clinicians ideally should be in equipoise about the treatments being tested,[3] and patients should give voluntary consent based on full disclosure of relevant information.[4] The practice of paying doctors to recruit patients under their care, and not disclosing this pecuniary interest, corrupts both these ideals.

Summary points

- Doctors are often paid to recruit patients to clinical trials sponsored by pharmaceutical companies
- Such payments are not at present disclosed to potential trial patients as part of the process of gaining consent
- Patients believe that such payments are wrong and that they have a right to be told about them
- Such non-disclosure is potentially unethical and damages efforts to involve patients more fully in clinical trials.

Paying recruiters is wrong in principle

Cash payments can potentially influence doctors' motives for joining a clinical trial. Some trials are designed by clinicians, often working with patients,[5] to answer important clinical questions. Other trials, especially in general practice, are different. They are sponsored and funded by pharmaceutical companies and are designed to achieve objectives that are at least in part commercially determined. Doctors who join have little or no control over the research question, design, methods, safety monitoring, analysis, reporting, or even the decision whether or not to publish the results.[6] Such trials depend on paying doctors to recruit patients. The size of the payment and not the buzz of research is what motivates doctors to join such trials.

Over the years we have seen the payments on offer soar to thousands of pounds per completed patient. Well organised British general practices can earn an extra £15 000 annually for three hours' work a week.[7] As a result, trials designed by non-commercial sponsors aiming to answer clinically important questions but without the funding available to pay recruiters fail to attract doctors.[8] So called postmarketing research (phase IV studies) is the biggest culprit. As uncontrolled observational cohort studies, these studies make no attempt to address important areas of clinical uncertainty. Their stated purpose is to familiarise doctors with new and recently licensed drugs.[9] This is marketing thinly disguised as research and is greatly helped by—and probably not possible without—a system of undisclosed payments.

A system that allows commercially driven and clinically dubious research to crowd out good and much needed clinical trials, and that denies patients the opportunity to put their altruism to the best possible use, is unethical and unacceptable.

Not disclosing payments compounds the harm

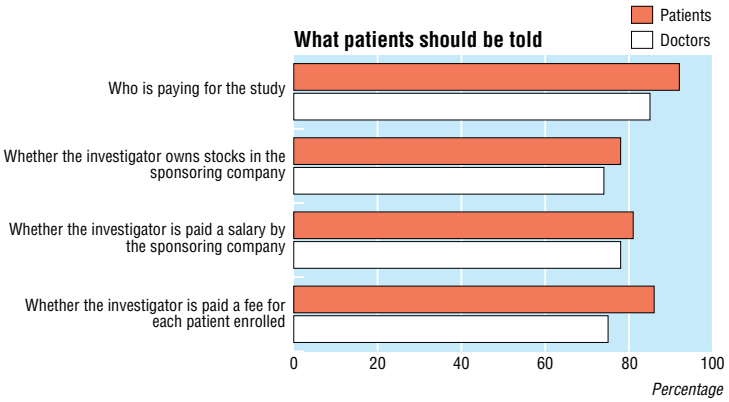
Because of the potential conflict of interest inherent in paying doctors to recruit patients in their care, guidelines on research ethics deal with this question.

The Royal College of Physicians' guidance,[10] for example, insists that such payments are divulged to a research ethics committee. It states that per capita payments, especially for postmarketing studies, are unethical; but reimbursement for time spent is acceptable and should be declared to an ethics committee.

Payments, often overtly on a per capita basis, have reached levels that are of serious concern to research ethics committees. Commercial sponsors regularly flout the implicit ban on per capita payments by claiming to pay for the work involved in conducting the trial (rather than for recruiting patients), and then overestimating the amount of time required for each patient. Such payments are in addition to the doctor's regular income and can result either in overwork or in displacing other more pressing clinical activity. Anecdotally we have heard that some hospital departments depend on regular income from patient recruitment and that some general practitioners have set up systems to trawl their databases to find patients who fit the requirements for a particular sponsor's study to improve their recruitment rates.

The lack of disclosure to patients can potentially be damaging. We acknowledge the potential for unethical practice by requiring that the amount and basis of payments are disclosed to a research ethics committee. However, this does not go far enough. Not to require a similar disclosure to patients is as cynical as it is demanding of blind and unquestioning trust. Patients who take part in trials do so at least partly from altruism.[11] Failure to reveal the conflict of interest that is inherent in payments that doctors receive from the trial sponsors is not a good basis for involving patients in the research endeavour. One American study found that just over half of patients questioned found payments to clinicians unacceptable. An even greater proportion (80%) believed that the patient had a right to know that their doctor would be paid for enrolling them (see figure).[9]

A change to the regulatory framework making full disclosure mandatory would not meet with opposition. Until 1997 it was the practice of one of our ethics committees (LJSC) to insist on full disclosure in the patient information sheet of the exact amount of payments to the investigator. In most cases neither the sponsor nor the investigator objected to this policy. The opportunity presented by the new system of multicentre research ethics committees to achieve a consistent approach on this question has not been taken up. The attitude still prevails that patients can always ask about payments if this is important to them. But it is disingenuous to expect patients to know that something they have not been told anything about is important enough for them to ask about.



What 200 patients and 394 doctors thought patients should be told about investigators' financial ties to research sponsors. From US study in 1995.[9]

Conclusion

Consent obtained on the basis of withholding information on an issue that patients consider important is not fully informed consent. If we are ever to reach the ideal of involving patients in the design and conduct of clinical trials[5] then we could do worse than treat patients as equal partners by making full and frank disclosure of payments that trial sponsors make to doctors for recruiting their patients.[12]

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One hundred years ago

Medicine men as scapegoats

SOME Indian tribes in America have an uncomfortable custom, when they are visited by an epidemic, of offering up a medicine man as a propitiatory sacrifice for the expiation of the sins of his tribe which are held accountable for the outbreak. In accordance with this custom, "Padre," a "big medicine man" of the Yuma Indians, who live on a reservation near Yuma, Arizona, was recently offered as a sacrifice on the occasion of an epidemic of small-pox. The "medicine man," divining the Indians' intention, fled to the mountains, but wandered back to the Indian village in a half-starved condition, and pleaded for mercy. He was promptly bound and conveyed by a delegation of Indians to Mexico, where he was tied to a tree and tortured, death ensuing after several hours of suffering. We have among us fanatics whose views as to the etiology of small-pox are even more absurd than those of the untutored Indians of Arizona, and who, if we may judge from the truculence of their invectives against the medical profession, would not be sorry to have the opportunity of treating the doctors as scapegoats in times of epidemic. (*BMJ* 1902;ii:205)